

## **REMARKS**

### **Claims**

Claims 74–84 are pending of which claims 1–73 were previously cancelled without prejudice or disclaimer. The claim identifiers recited herein are not to be construed with Applicants' acquiesce to the pending restriction requirement. Should the restriction requirement be withdrawn, either partially or entirely, the status of the claims will be amended to reflect such changes.

### **Amendments**

The claims have been amended to correct minor typographical errors. Use claims have been converted into process claims, in accordance with conventional US practice.

Claim 80 has been amended to eliminate multiple dependencies and further incorporates the structural elements recited in claim 74, to which it is dependent thereon.

It is respectfully submitted that the amendments do not recite new matter nor do they narrow the scope of the claims. Entry thereof is respectfully requested.

### **Formal matters**

Applicants respectfully disagree with the PTO's contention that the claims are recited in an "improper format." Based on the detailed disclosure contained in Applicants' own specification, further in view of the replete information in the art pertaining to the use of recognition molecules, the skilled worker appreciates that the various embodiments claimed herein can be practiced in the broadest possible scope. For example, *in vitro* diagnostic methods and *in vivo* method of treatment claims can be generically practiced by using recognition molecules having the structural (i.e., amino acid sequences) and functional (i.e., core-1 binding property) aspects claimed herein. Withdrawal of the objection is respectfully requested.

With respect to the use claims and the multiple dependent claims, Applicants thank the Examiner for his careful review of the claims. The forgoing amendments render these objections moot.

With respect to the sequence listing, Applicants have contacted a vendor for the provision of such disclosures. It is respectfully requested that the objection of the specification be held in abeyance until such can be furnished. See, MPEP §714.02 (b).

### **Election**

In response to this Restriction Requirement mailed June 23, 2008, Applicants hereby elect, with traverse, Group I (claims 71-79 and 80-84), drawn to a recognition molecule fused or associated

with immunoglobulin domains, wherein the recognition molecule binds the Core 1 antigen, and a method of producing/using such molecules.

Firstly, it is respectfully submitted that, in a generic Markush claim such as, for example, present claim 71, separation of the claim into separate groups (for example, Groups I-XVI), rather than an election of species, covering the entire scope of the claim, is improper. It is submitted that the restriction requirement violates rules 13.1 and 13.2, as explained in annex B of the administrative instructions under the PCT. Accordingly, it is clear that the restriction requirement must be withdrawn, and the same is respectfully requested.

Contrary to the implication in the Office action, a proper Markush claim **can** contain independent and distinct inventions. The PTO's own rules on this matter set forth in M.P.E.P. §803.02 specifically state that:

“A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. §103 with respect to the other member(s).”

This section of the M.P.E.P. makes clear that such a claim is a proper Markush claim and should be examined in accordance with Markush practice.

The requirement for restriction is further traversed insofar as the Office Action has not demonstrated that an undue searching burden would be required to examine all groups and certainly not to examine at least more than one of the groups (for example, Groups I-XVI, which are *generically* directed to a recognition molecule which binds to core 1 antigen). “If search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct invention.” (Emphasis added.) See, M.P.E.P. §803.

#### Election of species

Page 5 of the outstanding Office Action requires that Applicants elect ten sequences to comply with the election of species requirement. Insofar as the Office Action fails to provide any rationale as to why search/examination of anything *beyond* ten sequences would constitute an undue burden, this nebulous requirement is without merit. However, in order to comply with the election of species requirement, Applicants elect, with traverse, SEQ ID NO: 1; SEQ ID NO: 2; SEQ ID NO: 4; SEQ ID NO: 7; SEQ ID NO: 10; SEQ ID NO: 12; SEQ ID NO: 47; SEQ ID NO: 50;

SEQ ID NO: 80 and SEQ ID NO: 81.

It is respectfully submitted that limitation to ten specific sequences for examination is not justified. Applicant submits that the sequences recited in claims 74 and 75 should be searched and examined since these sequences each define CDR regions (for example, CDR1, 2 and 3) of an antibody which specifically binds to Core-1. A skilled worker recognizes that CDR regions are responsible for the binding of an antibody to its antigen (in the present case, Core- 1). Thus, all sequences defined in the claims of Group I are, contrary to the Examiner's view, linked by a common technical feature. In the present context, the Applicants' originally-filed application, for example, the paragraphs bridging pages 80 to 92 of the specification, fully describe this technical feature.

The argumentation with respect to the sequences defined in claims 74 and 75 further applies to claim 77. Claim 77 defines pairs of variable heavy and light chains of the so-called Karo-antibodies according to the present invention. Both the heavy as well as the light chains of the pairs defined in claim 77 are related and unlikely to pose a searching burden. The common linking feature of the pairs of variable heavy and light chains is, again, in accordance with the above explanations in respect of claims 74 and 75, the property to specifically bind to Core- 1.

Interestingly the present Office Action acknowledges the specific relationship of the sequences, thereby stating that in addition to the specifically selected sequences those sequences, which are patentably indistinct from the selected sequences, will also be examined (see page 6, 2d paragraph of the Office Action). In this con section, Applicant submits that the alternatives fir the CDR regions are indistinct from each other with respect to their patentability since they show only slight differences with respect of their sequences among each other.

As a further season for the limitation to only ten sequences, the Examiner notes that it would be a serious search and examination burden if the restriction were not required (section 10 of the Office Action). However, the Office Action fails to provide any evidence to justify the contention that the present claims lack of unity of Invention. As such, the restriction requirement is unjustified. Withdrawal thereof is earnestly solicited.

Should the Restriction Requirement still be maintained, Applicants will seek reentry of any withdrawn claims once allowable subject matter has been determined.

The Commissioner is hereby authorized to charge any fees associated with this response to Deposit Account No. 13-3402.

Respectfully submitted,

/Anthony J. Zelano/

---

Anthony J. Zelano, Reg. No. 27,969  
Attorney for Applicant(s)

MILLEN, WHITE, ZELANO  
& BRANIGAN, P.C.  
Arlington Courthouse Plaza 1, Suite 1400  
2200 Clarendon Boulevard  
Arlington, Virginia 22201  
Telephone: (703) 243-6333  
Facsimile: (703) 243-6410

Attorney Docket No.: VOSSM-0002

Date: July 29, 2008